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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/737,297	12/15/2000	Mark John Berry	F3247(C)	1757

201 7590 03/25/2004

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EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/737,297	BERRY ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *1-3 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-7 and 9-12* is/are rejected.

7)☒ Claim(s) *4,11 and 12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0219*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

Applicants' provisional election with traverse of Group II (claims 4-7 and 9-12) in response to office action dated October 1, 2003, filed on January 2, 2004 is acknowledged. The traversal is on the basis that the relationship between the subject matter of the two groups is such that it would not be unduly burdensome to conduct searches of both groups together. Applicants' arguments have been fully considered but not found persuasive. As for the search burden, inventions I and II are directed to different subject matter as shown by different classification. Therefore, examination of both groups together would present a search burden, because the searches of both the patent and non-patent technical literature are not co-extensive. For example a search for DNA does not result in a search of all literature for the protein. In addition a protein and a DNA cannot be substituted one for the other as each has different physical, chemical and biological properties and functions.

The restriction requirement is still deemed proper and is therefore made **FINAL.**

Therefore, claims 4-7 and 9-12 are under examination for the merits.

Claim Rejections - 35 USC § 101 (nonstatutory)

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4-6, 9, 11 and 12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims recite "protein" which reads on the naturally occurring proteins. The rejection would be obviated by the insertion of language indicating that the protein was isolated and purified. These claims are written as dependent from process claims and have been treated as product by process claims. The process steps recited in the claims do not differentiate the claimed product protein from the naturally occurring product.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an anti-freeze full length protein having N-terminal sequence of SEQ ID NO: 3 isolated from a bacterial culture; does not reasonably provide enablement for the isoforms and derivatives of the amino acid sequence of SEQ ID NO: 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The invention includes a protein having anti-freeze property, obtained by the process of claim 1 (claim 4), wherein the protein is heat-stable (claim 5), wherein the protein having a sequence homology in the N-terminal amino acid sequence of at least 75% to the amino acid sequence of SEQ ID NO: 3 (claim 6), wherein the isoforms and derivatives of the amino acid sequence of SEQ ID NO: 3 having anti-freeze properties (claim 7). The invention also includes a food product comprising a protein of claim 4, showing antifreeze property (claim 9), wherein the food product is selected from the group comprising frozen vegetables and frozen confectionery such as ice-cream (claim 10). The specification, however, only discloses cursory conclusions, without data to support the findings. See the discussion below.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include: 1) the nature of the invention; 2) the breadth of the claims; 3) the predictability or unpredictability of the art; 4) the amount of direction or guidance presented; 5) the presence or absence of working examples; 6) the quantity of experimentation necessary; 7) the state of the prior art; and, 8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

The nature of the invention:

The nature of the invention is defined by the claims, which include a protein having anti-freeze property, obtained by the process of claim 1, wherein the protein having a sequence homology in the N-terminal amino acid sequence of at least 75% to the amino acid sequence of SEQ ID NO: 3, wherein the isoforms and derivatives of the amino acid sequence of SEQ ID NO: 3 having anti-freeze properties. The specification fails to provide a description of the structure and function of the claimed variants (isoforms and derivatives). The nature of the variation makes it entirely unpredictable what might be considered a variant.

The breadth of the claims:

The breadth of the claims encompasses unspecified number of variants regarding the anti-freeze protein, which are not specifically described or demonstrated in the specification. The specification at page 9 describes that the invention comprises the novel protein 'marinomonin' having anti-freeze properties. It further comprises isoforms and derivatives, e.g.glycosylated forms of marinimonin possessing anti-freeze properties. However, the specification fails to describe any such glycosylated forms or any other derivatives possessing anti-freeze property. The specification also fails to describe the specific anti-freeze function of the derivatives generated from SEQ ID NO: 3. Claim 6 requires a fragment of the protein of SEQ ID NO: 3. The specification describes at page 9 that anti-freeze peptide isolated from *Marinomonas protea* shows an N-terminal amino acid sequence of SEQ ID NO: 3, and preferably the derivatives show at least 75%, more preferably 85% and in particular at least 95% homology in the N-terminal amino acid sequence with the 16 member amino acid sequence of SEQ ID NO: 3. However, the specification fails to provide the structure and/or function of these variants which have 75% or 85% or 95% homology to amino acid sequence of SEQ ID NO: 3. Given the lack of teachings or guidance in applicants' disclosure regarding the isoforms and derivatives of SEQ ID NO: 3 having anti-freeze property, it would require undue experimentation by one skill in the art to make derivatives of proteins of current invention or other undefined molecules having an activity substantially equivalent to that of the anti-freeze protein exemplified at pages 13-40 commensurate in scope with the claims. The specification has provided the process of generating full-length protein claimed, however, the specification fails to provide the positions in the sequence, which are critical to

the protein's structure/function relationship, such as sites or regions directly involved in binding and activity.

The amount of direction or guidance presented;

The presence or absence of working examples; and

The quantity of experimentation necessary:

Given the breadth of the claims in the invention, detailed teachings are required to be present in the disclosure in order to enable the skilled artisan to make and use the variants of broadly claimed group of anti-freeze proteins. Such teachings are absent in the specification. The specification has disclosed an anti-freeze protein having an amino acid sequence of SEQ ID NO: 3. There is no guidance as to how the functional derivatives would be generated for the anti-freeze protein of the invention. Claim 6 requires a fragment of the protein of SEQ ID NO: 3. The specification has provided no guidance to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein, which are tolerant to change (e.g. the active site), and the nature and extent of changes that can be made in these positions. The specification fails to provide adequate guidance for producing and screening for active protein variants that may be constructed. The working examples are exclusively drawn to making one full-length anti-freeze protein from bacterial isolates and characterizing (see Examples 1-9). However, the specification lacks a working example that demonstrates the claimed derivative protein.

State of the prior art:

The prior art has shown a protein having anti-freeze property (see section below of 102 rejection), however, the general knowledge and level of the skill in the art do not supplement the omitted description. The specification needs to provide specific guidance on the structure and function of protein prducts to be considered enabling for variants.

In consideration of each of factors, it is apparent that undue experimentation is necessary because in summary, the scope of the claim is broad, the working example does not demonstrate the claimed variants, the guidance/the teaching in the specification is limited, and the outcome is unpredictable for

the various modified forms. It is necessary to have additional guidance to carry out further experimentation to assess the property of the variants. Therefore, due to large quantity of experimentation necessary to generate the infinite number of variants and screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required to in order to provide activity, the absence of working examples directed to same, the complex nature of the invention and the breadth of the claims, which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

Claims 4, 6, 7, 10, 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite. The use of word "showing" renders the claim indefinite. A correction as to read "having" instead is suggested. Claim 4 is also rejected because it depends from a non-elected claim. It is suggested to rewrite claim 4 in independent format.

Claim 6 is indefinite because of incorrect use of sequence identifier. "sequence ID no 3" should be corrected to "SEQ ID NO: 3". Claim 6 is indefinite because of the use of the phrase "N terminal amino acid sequence." This renders the claim indefinite, it is unclear what amino acid sequence the N-terminal fragment of protein has, that would be at least 75% identical to SEQ ID NO: 3. Claim 6 is also indefinite as to the term "identical." "Identical is an absolute term. Acorrection to read "having 75% identity to" is suggested.

Claim 7 is indefinite because of incorrect use of sequence identifier. "SEQ ID no 3" should be corrected to read as "SEQ ID NO: 3." Claim 7 is also indefinite because it is not clear that what would

be the structure and function of the isoforms and derivatives of the sequence set forth in SEQ ID NO: 3.

Regarding claim 10, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 11 is indefinite because it depends from a non-elected claim 2. Also it is not clear in claim 2 whether the bacterial culture protein has $\geq$ 90% or 95% homology with SEQ ID NO: 1. Use of word "homology" also renders the claim indefinite. A correction to read "identity" is suggested.

Claim 12 is indefinite because it depends from a non-elected claim 3. Also it is not clear in claim 3 whether the bacterial culture protein has $\geq$ 90% or 95% homology with SEQ ID NO: 2. Use of word "homology" also renders the claim indefinite. A correction to read "identity" is suggested.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4 and 12 are rejected under 35 U.S.C. 102(b) as anticipated by Xu et al. (Can. J. Microbiol. Vol 44, pp 6473, June, 1998, IDS Ref. 13). Xu et al. teach an anti-freeze protein secreted to the growth medium by the plant growth promoting rhizobacterium *Pseudomonas putida* (see abstract, col 1, page 35). Xu's protein is considered for the protein that has antifreeze properties (claim 4). This protein is also considered for the protein having anti-freeze properties isolated from a bacterial culture of Pseudomonas species (claim 12), thus anticipating claim 4 and 12 of instant application.

Claims 4, 5 are rejected under 35 U.S.C. 102(b) as anticipated by Griffith et al. (Biotechnology Advances, Vol 13, No. 3, pp 375-402, 1995, IDS Ref. 12). Griffith et al. teach a recombinant type III AFP with two additional amino acids expressed in E. coli was found to have a stronger effect on ice crystal growth and enhanced resistance to heat denaturation when compared with the native ocean pout AFP (see page 389). This recombinant type III AFP is considered for the protein of claims 4 and 5 of instant application, thus anticipating the claims 4 and 5.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffith et al (Biotechnology Advances, Vol 13, No. 3, pp 375-402, 1995, IDS Ref. 12). Griffith et al. teach an anti-freeze protein that may improve the quality of foods that are eaten while frozen by inhibiting the recrystallisation and maintaining a smooth texture (see abstract). This frozen food is considered for the food product comprising a protein showing anti-freeze properties in the instant application (claim 9). Griffith et al. also teach that the inhibition of ice recrystallisation may be an important factor determining the texture of frozen food, especially foods such as ice-cream and popsicles that are eaten

while frozen (claim 10). The presence of AFPs in these products may inhibit ice crystal growth and preserve the smooth, creamy texture of a high quality product (see page 387).

Thus, it would have been obvious to a person having ordinary skill in the art at the time applicant's invention was made to have used the teachings of Griffith et al., to have a food product comprising the anti freeze protein (AFP) as in claim 9 of instant application. Also it would have been obvious to a person having ordinary skill in the art to substitute the AFP of Griffith et al. with a protein having anti-freeze property and which is heat stable (as in claim 5 instant application), and combine the teaching of Griffith et al. which suggests that an AFP may improve the quality of the frozen food by inhibiting the recrystallisation, because one skilled in the art recognizes the structural similarity of AFPs and would know that any protein having anti freeze property would be used in frozen food as well (as in claim 10). One would be motivated to use the AFP of instant application as an additive to the frozen food products.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (571) 272-0951. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 872-9306. Any inquiry of

a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0547

Rita Mitra, Ph.D.

March 17, 2004

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER